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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,558	03/14/2001	Michael M. Becker	GP068-05.CN3	3920

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GEN PROBE INCORPORATED
10210 GENETIC CENTER DRIVE
SAN DIEGO, CA 92121

EXAMINER

CALAMITA, HEATHER

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/808,558

Applicant(s)

BECKER ET AL.

Examiner

Heather G. Calamita, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 422-429, 431-433, 440-452, 459 and 461-479 is/are pending in the application.
- 4a) Of the above claim(s) 441-448, 450-452, 459, 461-465 and 473-479 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 422-429, 431-433, 440, 464 and 466-472 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. Currently, claims 422-429, 431-433, 440-452, 459 and 461-479 are pending. Claims 441-448, 450-452, 459, 461-465 and 473-479 are withdrawn as being drawn to non-elected subject matter. Claims 422-429, 431-433, 440, 464 and 466-472 are currently under examination. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 422-429, 431-433, 440 and 466-472 are rejected under 35 U.S.C. 103(a) as being unpatentable over Agrawal et al. (WO 94/01550) in view of Tyagi et al. (U.S. Patent Number 5,925,517).

Agrawal et al. teach (claim 422) a hybridization assay probe for use in determining the presence of a nucleic acid analyte in a sample, the probe comprising a first and second base regions capable of hybridizing to each other under nucleic acid assay conditions to form a hybrid containing at least one ribonucleotide modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety, wherein the probe forms a stable double-stranded complex with the nucleic acid analyte but not with a non-targeted nucleic acid under nucleic acid conditions, wherein the complex comprises a single stranded form of the probe (see page 15, lines 1-30 and p. 16 lines 24-35). With respect to the complex comprising a single stranded form of the probe see Figure 1.

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With regard to claim 423, Agrawal et al. teach the portion of the first base region includes a cluster of at least about 4 ribonucleotides modified to include a 2'-O-alkyl substitution to the ribofuranosyl moiety (see page 16, lines 24-36).

With regard to claim 424, Agrawal et al. teach at least on nucleotide which is not a ribonucleotide modified to include a 2'-O alkyl substitution to the ribofuranosyl moiety (see page 16, lines 24-36).

With regard to claims 425 and 426, Agrawal et al. teach ribonucleotides modified to include a 2'-O alkyl substitution to the ribofuranosyl moiety (see page 16, lines 24-36).

With regard to claim 427, Agrawal et al. teach the probe includes a conjugate molecule (s see page 17, lines 1-12).

With regard to claim 428, Agrawal et al. teach the probe includes a conjugate molecule joined to the probe at a site located within the cluster of the first base region (see page 17, lines 1-12).

With regard to claim 429, Agrawal et al. teach the first and second base regions are contained within an oligonucleotide that is between 10 and 100 bases in length (see p. 15 line 30).

With regard to claim 431, Agrawal et al. teach the label comprises a fluorescent molecule (see p. 17 line 9).

With regard to claims 432 and 433, Agrawal et al. teach the nucleic acid analyte comprises RNA and ribosomal RNA (see page 10, lines 14-36).

With regard to claims 440, 467-472, Agrawal et al. teach the 2'-O-alkyl substitution to the ribofuranosyl moiety is a 2'-O-methyl substitution (see p. 16 lines 25-29).

With regard to claim 464, Agrawal et al. teach a target sequence contained within the nucleic acid analyte includes a double stranded region (see page 8, lines 23-35 and Figure 6).

With regard to claim 466, Agrawal et al. teach the hybrid formed between the first and second base region is more stable than a hybrid formed between unmodified forms of the first and second base regions (see page 16, lines 24-36).

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Since the structure of the claimed probe was disclosed by Agrawal et al., the claimed functions “for use in determining the presence of nucleic acid analyte in a sample” would have been an inherent property of the oligonucleotide taught by Agrawal. Note MPEP 2112.01 states in part “...[w]here the claimed and prior art products are identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.”

Agrawal et al. does not teach an oligonucleotide probe comprising a detectable label, namely a fluorescent molecule.

Tyagi et al. teach oligonucleotides comprising self-complementary regions and further comprise a detectable label, namely a fluorescent label (see column 15 and 16, lines 40-43 and 23-27, respectively).

One of ordinary at the time the invention was made would have been motivated to incorporate a detectable label, as taught by Tyagi et al. into an oligonucleotide, as taught by Agrawal et al. in order to detect the hybridization of a probe to the target nucleic acid since Tyagi et al. specifically teach the detection of a probe that is hybridized to a target nucleic acid (see Example VIII). It would have been *prima facie* obvious to incorporate a detectable label, as taught by Tyagi et al. into an oligonucleotide, as taught by Agrawal et al. to detect the hybridization of the oligonucleotide probe to a target nucleic acid because as exemplified by Tyagi in Example VIII, oligonucleotides containing detectable labels are useful for detecting the hybridization of a probe to a target nucleic acid.

Response to Arguments

3. Applicant's arguments with respect to the 102 (b) rejections over Agrawal have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling

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hgc



JEFFREY FREDMAN
PRIMARY EXAMINER

4/2/08